

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MICHELLE MCMUNN, et al.,)	
Plaintiffs,)	Civil Action No. 10-143
vs)	
)	
BABCOCK & WILCOX POWER)	
GENERATION GROUP, INC., et al.,)	
Defendants.)	
)	
JESSI ANN CASELLA, et al.,)	
Plaintiffs,)	
vs)	Civil Action No. 10-368
)	
BABCOCK & WILCOX POWER)	
GENERATION GROUP, INC., et al.,)	
Defendants.)	
)	
MICHAEL P. HUTH, et al.,)	
Plaintiffs,)	
vs)	Civil Action No. 10-650
)	
BABCOCK & WILCOX POWER)	
GENERATION GROUP, INC., et al.,)	
Defendants.)	
)	
LINDA W. DILICK,)	
Plaintiff,)	
vs)	Civil Action No. 10-728
)	
BABCOCK & WILCOX POWER)	
GENERATION GROUP, INC., et al.,)	
Defendants.)	
)	
BONNIE AIKENS, et al.,)	
Plaintiffs,)	
vs)	Civil Action No. 10-744
)	
BABCOCK & WILCOX POWER)	
GENERATION GROUP, INC., et al.,)	
Defendants.)	
)	
PATRICIA ALTIMIRE, et al.,)	
Plaintiffs,)	

vs)	Civil Action No. 10-908
)	
BABCOCK & WILCOX POWER)	
GENERATION GROUP, INC., et al.,)	
Defendants.)	
)	
HEATHER LORRAINE BAYNAR, et al.,)	
Plaintiffs,)	
vs)	Civil Action No. 10-1736
)	
BABCOCK & WILCOX POWER)	
GENERATION GROUP, INC., et al.,)	
Defendants.)	
)	
MARCIA BAUSTERT, et al.,)	
Plaintiffs,)	
vs)	Civil Action No. 11-898
)	
BABCOCK & WILCOX POWER)	
GENERATION GROUP, INC., et al.,)	
Defendants.)	
)	
SANDRA L. AMENT, et al.,)	
Plaintiffs,)	
vs)	Civil Action No. 11-1381
)	
BABCOCK & WILCOX POWER)	
GENERATION GROUP, INC., et al.,)	
Defendants.)	

MEMORANDUM AND ORDER

Plaintiffs bring these actions alleging that Defendants, Babcock & Wilcox Power Generation Group, Inc., B&W Technical Services, Inc. and Atlantic Richfield Co., as successors in interest to the Nuclear Materials Corporation (“NUMEC”), are responsible for the release of radioactive, hazardous and toxic substances into the environment surrounding two nuclear materials processing facilities located in the Borough of Apollo and in Parks Township, Pennsylvania, during the operation, remediation and/or decommissioning of these facilities. Plaintiffs allege that the releases have contaminated the air, soil, surface water and ground water

in the surrounding communities and caused them personal injuries and property damages.

Plaintiffs assert jurisdiction under the Price Anderson Act, 42 U.S.C. § 2210(n)(2), and the Atomic Energy Act, 42 U.S.C. § 2011, and also assert state law claims of negligence, negligence per se, strict liability, civil conspiracy, and wrongful death and survival, for which supplemental jurisdiction is asserted pursuant to 28 U.S.C. § 1367(a).

Currently pending before the Court for disposition are motions, filed by the Defendants in each case, which contend that Plaintiffs have failed to fully comply with this Court's January 24, 2012 Case Management Order (CMO) regarding their responsibility to set forth a prima facie case in support of their claims, particularly on the issues of each Plaintiff's exposure, dose and theory of causation. Defendants request that the Court narrow the issues by precluding Plaintiffs from pursuing, offering or relying upon evidence relating to theories of exposure, dose or causation that are not supported by prima facie evidence. The motions have been fully briefed. For the reasons that follow, they will be granted in part and denied in part.

On January 24, 2012, the Court entered a CMO requiring that, within 90 days, each Plaintiff provide Defendants with admissible evidence, in the form of expert affidavits or otherwise, establishing the prima facie elements of his or her claims, including:

- a. an identification by name of the specific radionuclide(s) released from Defendants' facilities in excess of the applicable federal permissible limits;
- b. an identification of each exposure pathway(s) through which each Plaintiff was exposed to each specific radionuclide;
- c. the facility from which the radionuclide(s) originated and the dates of each Plaintiff's exposure to those specific radionuclides originating from that facility;
- d. the numerical dose, if any, for each Plaintiff's claimed exposure to the specific radionuclides originating from that facility;
- e. the epidemiological evidence demonstrating that the specific radionuclide(s) to which the Plaintiff was exposed causes the Plaintiff's specific disease(s) (general

causation) and that the exposure(s) and resulting dose (if any) caused the Plaintiff's specific disease(s) (specific causation); and

f. the scientific and medical evidence providing the basis for and supporting each such *prima facie* element of his or her claim.

2. Plaintiffs['] submittal pursuant to this Order shall not use phrases such as "including, but not limited to" or "including without limitation" when responding to items 1(a)-(e) above. Plaintiffs shall be prohibited from asserting any theory of exposure, dose, or causation that is not specifically stated in Plaintiffs' response to the Court's Order and supported by admissible evidence of a *prima facie* theory.

Plaintiffs, who had objected to the CMO, filed motions for clarification of the CMO and "motions to determine standards and procedures for adjudication of the sufficiency of Plaintiffs' *prima facie* materials," and these motions were denied by the undersigned. In addition, they filed objections to the CMO, which were overruled by the district judges in each case. See Civ. A. No. 10-143, ECF No. 147; Civ. A. No. 10-368, text-order dated May 15, 2012; Civ. A. No. 10-650, ECF Nos. 112, 113; Civ. A. No. 10-728, ECF No. 131; Civ. A. No. 10-744, ECF No. 128; Civ. A. No. 10-908, ECF No. 145; Civ. A. No. 10-1736, ECF No. 116; Civ. A. No. 11-898, text-order dated May 15, 2012; Civ. A. No. 11-1381, ECF No. 41.

On April 24, 2012, Plaintiffs submitted five expert reports in support of their claims (from Dr. Howard Hu, Dr. Paul Doetsch, Mr. Bernd Franke, Dr. Michael Ketterer and Dr. Joseph Ring) and on May 8, 2012, they submitted a sixth report from Dr. James Melius. Defendants filed motions regarding the five reports on May 30, 2012 and submitted supplements regarding the sixth report on June 14, 2012. Plaintiffs filed their briefs in opposition on July 23, 2012, and Defendants filed reply briefs on August 21, 2012. Although Defendants requested oral argument in connection with these motions, the undersigned has determined that oral argument is not necessary and the motions can be decided based upon the briefs and evidence submitted by the parties.

Standard of Review

Plaintiffs contend that Defendants' motions improperly challenge their claims in the manner of a motion for summary judgment under Federal Rule of Civil Procedure 56 or that they improperly seek to limit the evidence they may offer at trial in the manner of a motion in limine. Defendants respond that the motions properly address whether Plaintiffs have complied with the CMO.

As noted above, the CMO itself stated that Plaintiffs would be prohibited from asserting any theory of exposure, dose or causation that was not specifically stated in their response to the CMO and supported by admissible evidence. (CMO ¶ 2.) Thus, Defendants' motions are neither motions for summary judgment under Rule 56 nor motions in limine, but rather the appropriate mechanism to probe whether Plaintiffs have complied with the CMO. See Fed.R.Civ.P. 16(c)(2)(A) (the Court may adopt procedures for the purpose of "formulating and simplifying the issues, and eliminating frivolous claims or defenses.")

As explained by the Court of Appeals for the Fifth Circuit:

The pre-discovery orders in issue are of a type known as Lone Pine orders, named for Lore v. Lone Pine Corp., 1986 WL 637507, No. L-33606-85 (N.J. Super. Ct. 1986). Lone Pine orders are designed to handle the complex issues and potential burdens on defendants and the court in mass tort litigation. In the federal courts, such orders are issued under the wide discretion afforded district judges over the management of discovery under Fed.R.Civ.P. 16.

In these two cases, treated as related in the district court, there are approximately one thousand six hundred plaintiffs suing over one hundred defendants for a range of injuries occurring over a span of up to forty years. Neither the defendants nor the court was on notice from plaintiffs' pleadings as to how many instances of which diseases were being claimed as injuries or which facilities were alleged to have caused those injuries. It was within the court's discretion to take steps to manage the complex and potentially very burdensome discovery that the cases would require. See Landry v. Air Line Pilots Ass'n Int'l AFL-CIO, 901 F.2d 404, 436 (5th Cir. 1990); Fournier v. Textron, Inc., 776 F.2d 532, 534 (5th Cir. 1985) (noting district court's authority to manage and develop complex litigation discovery).

The scheduling orders issued below essentially required that information which plaintiffs should have had before filing their claims pursuant to Fed.R.Civ.P. 11(b)(3). Each plaintiff should have had at least some information regarding the nature of his injuries, the circumstances under which he could have been exposed to harmful substances, and the basis for believing that the named defendants were responsible for his injuries. See Beanal v. Freeport-McMoran, Inc., 197 F.3d 161, 165 (5th Cir. [(1999)]) (plaintiff's complaint is insufficient where it is devoid of "names, dates, locations, times, or any facts that would put [defendant] on notice as to what conduct supports ... his claims"). The affidavits supplied by plaintiffs did not provide this information. The district court did not commit clear error or an abuse of discretion in refusing to allow discovery to proceed without better definition of plaintiffs' claims.

Acuna v. Brown & Root, Inc., 200 F.3d 335, 340-41 (5th Cir. 2000). See also Avila v. Willits Env'tl Remediation Trust, 633 F.3d 828, 833-35 (9th Cir. 2011) (affirming application of Lone Pine order and district court's dismissal of claims due to plaintiffs' failure to make a sufficient prima facie showing of exposure and causation).

Plaintiffs note that the Price Anderson Act (PAA) indicates that "the substantive rules for decision in [a public liability action] shall be derived from the law of the State in which the nuclear incident involved occurs, unless such law is inconsistent with the provisions of section [2210]." 42 U.S.C. § 2014(hh). Thus, they contend that they need only present a prima facie case of negligence under Pennsylvania law. Plaintiffs then describe how the PAA and Pennsylvania law intersect, in that: 1) demonstrating that a defendant caused a nuclear release in excess of applicable federal statutes establishes two of the four elements necessary to bring a PAA case in Pennsylvania, namely duty by the defendant and breach; 2) under the PAA, a plaintiff must show a violation of 10 C.F.R. § 20.105 (which limits the amount of radiation a licensee may allow to be released in the area of its facility) or 10 C.F.R. § 20.106 (which provides that licensees shall not possess, use or transfer licensed material so as to release to an unrestricted area radioactive material in concentrations which exceed the limits specified in a

table attached to the regulation); and 3) proving causation under Pennsylvania law does not require a plaintiff to show that radiation was the exclusive cause of harm, only a “substantial factor” as indicated in the Restatement (Second) of Torts § 431(a) and thus evidence that, to a reasonable degree of medical certainty, the alleged negligence increased the risk of injury actually sustained is sufficient even if the actual procuring cause of the injury cannot be determined and no particular degree of increased risk is required. They assert that they have shown by expert testimony that each of them was exposed to ionizing radiation released from Defendants’ plants in violation of the law, that their exposures to radiation increased the risk that each would contract the cancers they did, and that the exposure was a substantial contributing factor in causing each Plaintiff’s cancer. They also argue that they have made a proper prima facie case of recklessness under Pennsylvania law and the relevant provisions of the PAA because deliberately exposing people to radiation in excess of permitted levels in the course of operating a plant has been found sufficient to make out a claim for punitive damages in Pennsylvania, and they have proffered evidence that Defendants chose the economic benefit of continued plant operation over public safety by knowingly exposing Plaintiffs and their community to unlawful levels of radiation on an ongoing basis.

However, Plaintiffs’ arguments miss the mark. Defendants are not arguing that Plaintiffs have violated the Lone Pine CMO by failing to present any evidence that any Plaintiff suffered exposure to radiation from any facility operated by Defendants that increased the risk that the individual would contract any cancer, thereby calling for the dismissal of the cases utilizing a standard higher than that required under Pennsylvania law or the PAA.¹ Rather, they are

¹ Some of Defendants’ arguments do address the merits of the cases, such as their argument that Dr. Melius’s differential diagnosis methodology is inadequate. The Court will not discuss these arguments herein.

arguing, as anticipated by the CMO, that Plaintiffs' claims should be narrowed to proceed with the prima facie cases that are met, but not for the radionuclides, pathways and exposure doses that are not supported by prima facie evidence. Therefore, the Court will proceed to review Plaintiffs' evidence to determine the extent to which it complied with the CMO.

Summary of Plaintiffs' Expert Reports

Joseph P. Ring, Ph.D.

Dr. Ring was retained by Plaintiffs to offer an expert opinion regarding alleged releases of radiation from Defendants' facilities at Parks and Apollo (i.e., a source term expert). Plaintiffs contend that Dr. Ring indicated that radioactive materials including plutonium and highly enriched uranium were used at both Parks and Apollo (Ring Rpt. at 5); that the operational, health and safety practices of the facilities did not comply with industry standards for much of the time they were operated (id. at 5, 9, 12); that the radiation protection programs were not adequate to monitor the radioactive material used and management knew this to be the case (id. at 5, 6, 21); that compliance records showed several large-scale releases of ionizing radiation into surrounding neighborhoods (id. at 5); that NUMEC was regularly issued violations of federal regulations and also regularly failed to comply with orders from the Atomic Energy Commission and/or the Nuclear Regulatory Commission on matters related to health and safety (id.); that NUMEC's environmental monitoring was also inadequate and improperly accounted for the extent of environmental releases (id. at 6); that NUMEC's failure to properly monitor and report levels of radiation led employees at the facilities to be placed in a special exposure cohort by the United States Department of Health and Human Services and, as such, were "presumed to have sufficient radiation exposure to cause a reasonable likelihood it may have endangered their health" if they were employed 250 or more days at the plant (id.); that NUMEC's improper

operations resulted in illegal dumping of radioactive materials in the soil and water around the plants and there were also excessive and unlawful emissions of radioactive materials from plant stacks (id.); that where monitored, data shows frequent unlawful emissions well above federal regulatory limits in unrestricted areas (id. at 7); that NUMEC affirmatively hid the nature and extent of violations of health and safety regulations (id.); that at one point, NUMEC had the highest level of nuclear “Materials Unaccounted For” (“MUF”) of any facility in the United States (id.); and, that “Based on the inadequate monitoring system, large number of unmonitored release points, and significant quantities of radioactive materials deposited in the ventilation system, and in view of NUMEC’s failure to provide a plausible explanation for the MUF, it is reasonable to infer that most of this MUF was released into the communities surrounding these facilities.” (Id.)

Defendants respond that Dr. Ring does not identify any release of radioactive materials to which Plaintiffs’ experts claim that any particular individual Plaintiff was actually exposed. They note that he references a hypothetical dose calculation prepared by Bernd Franke (described below), but he does not tie this calculation to any specific Plaintiff. (Ring Rpt. at 19.) He testified that he has no opinion on dose. (Ring Dep. at 65:7-13.) Dr. Ring testified that he has no opinion whether radionuclides were released from Parks. (Ring Dep. at 62:20-63:13; 132:10-11; 196:9-10 (“I didn’t look at Parks.”). He further testified that his opinions are related solely to claimed uranium emissions from Apollo during its period of operations. (Ring Dep. at 58:19-59:15; 60:11-19; 64:7-20; 124:14-18; 132:12-19.)

Michael Ketterer, Ph.D.

Dr. Ketterer is a chemist who was retained by Plaintiffs to provide an expert report, analysis and opinion “about sources of uranium and plutonium near [the Apollo and Parks

facilities.]” (Ketterer Rpt. at 3.) Dr. Ketterer analyzed soil samples he took around the Apollo and Parks facilities in March 2012 after the Court issued the CMO.

Dr. Ketterer concluded that:

1. With reasonable scientific certainty enriched uranium (EU) was found “widespread in soils” in and around Apollo. Mass spectrometry indicated this EU could be distinguished from uranium deposits that would be naturally occurring, (i.e., background);
2. EU was “consistently found” in soil depths of 0-5 cm within a 2.5 km radius of Apollo and was “present” in soil depths greater than 5 cm within the same radius of the former plant;
3. A consistent chemical “signature” indicated that the EU found in the soil near the former Apollo facility was of the same composition as that in the estimated cumulative emissions identified by IEER (1998). More importantly, “the finding of EU in the environment requires a causative explanation associated with an anthropogenic (i.e., manmade) source. There is no other plausible explanation for the presence of EU in the Apollo environment besides its origin from the former NUMEC facility;
4. At least one sample indicated plutonium (“Pu”) activity “consistent with the nuclear fuels used at the former Parks facility and the atom ratio indicates that this Pu cannot originate exclusively from nuclear weapons tests;” and
5. Dr. Ketterer’s findings were consistent with the previously published 1994 CHMR and 1998 IEER studies at Apollo.

Plaintiffs contend that Dr. Ketterer provides crucial, unequivocal evidence that EU is found widely dispersed, and in a variety of depths within a 2.5 km radius of the site of the former Apollo facility. (Ketterer Rpt. at 6.) More importantly, his report provides sufficient data to show that the identified uranium is of a type that is not naturally-occurring and that “there is no other plausible explanation” for it to be in the environment around Apollo but for “its origin from the former NUMEC facility.” (*Id.* at 6.) They contend that Dr. Ketterer’s findings were consistent with previous, well-respected studies that this Court found acceptable in the Hall litigation. Dr. Ketterer stated at his deposition that his findings supported CMO ¶ 1(b) because

he identified an exposure pathway (“atmospheric”) for the release of uranium from the Apollo facility and its subsequent accumulation in the soil. (Ketterer Dep. at 74:7.)

Defendants contend that Dr. Ketterer confirmed that no Apollo uranium exists beyond 2.5 km from the site (Ketterer Dep. at 78:2-79:22), and he agreed that his study does not support the claimed release of any radionuclide, including plutonium, from Parks. (Id. at 85:6-89:20.) They indicate that his study proves the absence of atmospheric releases from the Parks facility. (Id. at 177:3-22.) He stated only that his study “could” support an airborne exposure pathway. (Id. at 75:3-23.)

Bernd Franke

Mr. Franke was retained by the Plaintiffs to provide an expert opinion that the amount of ionizing radiation in the form of enriched uranium that was released from the Apollo facility exceeded federal permissible regulations over the entire operational life of the facility. Moreover, Mr. Franke recreated the numerical dose that an individual Plaintiff would have received as a result of a specific incident recorded in the Apollo facility’s history. Mr. Franke previously co-authored a 1998 report, “Radiation Exposures in the Vicinity of the Uranium Facility in Apollo, Pennsylvania” (“1998 Report”), which he updated in his present affidavit.

Plaintiffs contend that Mr. Franke’s work supports the proposition that Apollo’s aerial emission regularly and routinely exceed federal permissible limits constituting a breach of duty under the TMI cases. In particular Mr. Franke concluded that during the operational years 1963 – 1979 Apollo violated 10 C.F.R. § 20.106 each and every year. (Franke Rpt. at 28 & Table 4.)

Mr. Franke states that:

The revised results clearly indicate that a[] short-term release of 3 kg of highly enriched uranium would have resulted in significant exposures and subsequent radiation doses to members of the public who were present in the vicinity of the plant during the accident. Up [to] and including 1979, the lung dose limit for

residents was 1.5 rem; the accidental exposure could thus have resulted in doses that were up to 280 times larger than the permissible lung dose for 1963.

(Frank Rpt. ¶ 7.)

Defendants note that, although Mr. Franke claims to be fully capable of calculating a Plaintiff-specific dose (and did so in the Hall case), he did not calculate a dose for any Plaintiff in these cases. He neither received nor reviewed Plaintiffs' depositions or questionnaire responses, nor did he make any effort to understand the specific cancers or diseases at issue in the case. (Franke Dep. at 28:25-29:10 ("I was not told that they [the Plaintiffs] were deposed and I wasn't asked to read the depositions if they exist."), 34:24-35:3 (confirming no knowledge of relevant Plaintiff organs). He did not ask to speak to a single Plaintiff. (Id. at 35:18-21.) They note that he admitted that his report does not provide "the numerical dose, if any, for each Plaintiff's claimed exposure to the specific radionuclides originating from that facility [in this case, Apollo]." (Id. at 29:22-30:2 (responding "It does not" when asked if his report addresses CMO ¶ 1(d)).

Defendants cite the fact that Franke's report repeats the same statement he made in his October 31, 2011 preliminary report: "I am prepared to provide a detailed assessment of the radiation exposures for specific individuals who lived near the Apollo and Parks facilities once I receive more information about the circumstances of the individuals at issue (age at exposure, location, residence time, living habits, etc.)." (Franke Rpt. ¶ 9.) In his report, Mr. Franke did calculate a hypothetical dose to a hypothetical person standing at one spot along the site boundary based on a claimed fifteen-minute release of uranium from Apollo in 1963 and hypothetical wind conditions. (Id. ¶ 6.) However, Defendants note that he admitted that this hypothetical calculation (referred to as a "scenario calculation") is irrelevant to the Plaintiffs because he made no attempt to associate the dose range with a single Plaintiff. (Franke Dep. at

45:13-19.)

Plaintiffs respond that Dr. Melius explained that, because of the inherent unreliability of the environmental monitoring data at the Apollo facility, there was minimal value in doing a numerical dose reconstruction in this case because any such analysis would significantly understate any individual's exposure. (Melius Dep. II at 376:18-378:7.)

Paul Doetsch, Ph.D.

Dr. Doetsch is a molecular cell biologist and one of Plaintiffs' two general causation experts. He states that:

Ionizing radiation is a proven human carcinogen (cancer causing agent). The evidence for this comes from many different sources, including epidemiological studies, case reports, animal studies, and other laboratory research.

Most scientists and regulatory agencies agree that even the smallest doses of ionizing radiation increase cancer risk by an amount proportional to the dose. In general, the risk of cancer from radiation exposure increases as the dose of radiation increases. There is no threshold below which ionizing radiation is believed to be safe.

(Doetsch Rpt. at 9.)

Dr. Doetsch identified several cancers that are caused by ionizing radiation. (Id.) Leukemia is the most common-such cancer and cancers of the thyroid gland and bone marrow are also particularly prevalent in the presence of ionizing radiation exposure. (Id.) Still other forms of cancer are directly attributed to radiation exposure, although they may take a comparatively longer time to develop. Among them are cancers of the bile ducts, bone, brain, breast, colon, esophagus, gall bladder, kidney, liver, lung lymphoma (Non-Hodgkin's), multiple myeloma, ovary, pancreas, salivary gland, small intestine, stomach, thyroid, and urinary tract. (Id.) In addition, the Doetsch Report clearly states, "these are not the only cancer types that may be linked to ionizing radiation, however." (Id.)

Defendants respond that Dr. Doetsch testified that his report does not address any of the CMO's requirements. (Doetsch Dep. at 25:22-30:1) (responding "no" to questions about whether his report addresses the CMO's subsections). He was not told which cancers are at issue in these actions. (Id. at 36:6-14.) Nor was he asked to offer an opinion about whether any particular Plaintiff's cancer or disease was, in fact, caused by radiation exposure that allegedly occurred three-plus decades ago. (Id. at 34:19-23.) He did not recall researching any specific publication addressing uranium. (Id. at 44:13-16.) And other than references in the general textbooks he brought to his deposition, Dr. Doetsch did not cite to – nor did he review – any epidemiological studies. (Id. at 46:8-13; 48:25-49:14.)

Howard Hu, M.D.

Dr. Hu is an environmental epidemiologist and Plaintiffs' second general causation expert. Dr. Hu concluded that the radionuclides of interest at the Apollo plant included highly enriched uranium, plutonium, and thorium. (Hu Rpt. at 2.) Of particular concern was highly enriched uranium which is "over 70 times more active radiobiologically (and, therefore, more carcinogenic) than [other isotopes of naturally-occurring uranium]." (Id.)

Dr. Hu's opinions explain the distinction between naturally occurring uranium and highly enriched uranium with respect to the tendency to cause cancer. (Id. at 7.) As he explained, the rate of emission of alpha particles from highly enriched uranium is much greater than in the naturally occurring form of the element, making it more dangerous. (Id.) Dr. Hu recognized that data was comparatively limited regarding highly enriched uranium but concluded, nevertheless, that "highly enriched uranium can be expected to have significant carcinogenic potential on account of its emission of ionized radiation in the form of alpha particles." (Id.) (emphasis in original.)

Dr. Hu concluded, based on his own research and that of others, that the types of radionuclides emitted at the Apollo facility could have caused a number of different cancers. (Id. at 14.) These included cancers of the bile ducts, bone, brain, breast, colon, esophagus, gall bladder, kidney, leukemia, liver, lung, lymphoma (Non-Hodgkin's), multiple myeloma, ovary, pancreas, pharynx, salivary gland, small intestine, stomach, thyroid, and urinary tract. (Id.) His report states that:

Regarding an individual who lived, worked, or otherwise spent a significant amount of time within the likely exposure area and who subsequently developed a cancer associated with ionizing radiation, it would be reasonable to conclude that ionizing radiation exposure from the emissions of radionuclides from the Apollo nuclear plant may have constituted a substantial contributing factor towards the causation of that cancer.

(Id.)

Defendants contend that Dr. Hu is not an expert in radiation epidemiology, and he admits that he has never studied a population for health effects from exposure to ionizing radiation. (Hu Dep. at 13:7-14:9; 152:24-153:1.) His report does not address whether any specific Plaintiff's type of cancer can be caused by exposure to a specific radionuclide. (Hu Rpt. at 1.) In fact, they note that he admits that he does not even know Plaintiffs' types of cancer. (Hu Dep. at 153:5-13.) Defendants further point out that Dr. Hu cites no epidemiological studies that support Plaintiffs' claim that exposure to uranium can cause each Plaintiff's alleged cancer or disease.

James Melius, M.D., Dr. P.H.

Plaintiffs retained Dr. Melius to render opinions on whether, based on his review of the medical, occupational, family and residential histories of each individual Plaintiff the specific exposures to radionuclide emissions from the Apollo and/or Parks facilities led to their various diagnoses of cancer. (Melius Rpt. at 3.) In order to form his expert opinion, Dr. Melius reviewed information and reports on the facilities, including those prepared by Mr. Franke, Dr. Hu, Dr.

Ketterer, and Dr. Ring. (Id.) He also relied on his reviews of Plaintiffs' medical records, depositions, questionnaires, and individual interviews. (Id.) In rendering his opinion, he relied on the technique of differential diagnosis, which he explained "is a fundamental part of medical practice whereby the examining physician evaluates all of the clinical data regarding a patient and weighs this information in order to reach a diagnosis and formulate a treatment plan for that patient (Thorn, 1977). In this instance, that approach is applied to the determination of the etiology of a particular disease in a patient." (Id. at 3.) Plaintiffs contend that this method of determining causation has been widely accepted by courts including Judge Ambrose in Hall v. Babcock & Wilcox Co., 69 F. Supp. 2d 716, 729 (W.D. Pa. 1999) ("As I have reviewed Dr. Melius's methodology as set forth above and the dictates of the law, I find that Dr. Melius's testimony, as set forth in his report, is reliable.")²

Dr. Melius's report primarily consists of an individual analysis of 73 named Plaintiffs. (Melius Rpt. at 4-51.) For each, he assessed a number of risk factors for the cancer each Plaintiff suffered, including potential incidents of exposure to radionuclides from the Apollo and Parks facilities, and concluded, in each instance, that the Plaintiff's cancer could be attributed, at least in part, to such exposure.

Plaintiffs contend that Dr. Melius's expert opinion provides sufficient evidence that, if taken as true, allows them to meet the burden of establishing the causation element such that a judge would be warranted in letting a trial go to the jury. Stewart v. Abraham, 275 F.3d 220, 229 (3d Cir. 2001).

² Defendants note that, in Hall, Dr. Melius testified at trial regarding a flawed epidemiological study that he prepared, but failed to disclose in his Rule 26 report, resulting in the Court's June 29, 1999 opinion vacating the jury verdict and ordering a new trial. See Hall, 69 F. Supp. 2d at 722-24. They also challenge the validity of differential diagnosis as a methodology. However, that issue is not before the Court at this time.

Defendants argue that Dr. Melius fails to cite any epidemiological studies involving exposure to uranium that he claims support his opinions. Moreover, they contend that he admits that he made no effort to determine whether his conclusions are consistent with the epidemiological literature on uranium. (Melius Dep. Vol. II at 49:10-14.)

Defendants contend that Dr. Melius' opinions also are flawed because they are not based on radiation doses received by any Plaintiff. Dr. Melius acknowledges that his opinions were formed without any consideration of Plaintiff-specific doses. (Melius Dep. Vol. I at 106:8-15) (Q: "So it's correct that you derived the opinions stated in your report without an estimated dose for any of the individual Plaintiffs; correct?" A: "Correct, if I believe I understand what you believe to be an estimated dose, yes.") (objection omitted).

CMO ¶ 1(a): Identifying Radionuclides

Plaintiffs contend that, in their reports, Dr. Ring identified the radionuclides released as highly enriched uranium and plutonium, Dr. Ketterer identified highly enriched uranium at a distance of 2.5 kilometers from the Apollo facility, and Mr. Franke identified highly enriched uranium as having been released in excess of federal permissible limits between operational years 1963 and 1979 at the Apollo facility.

Defendants respond that Dr. Ring testified at his deposition that his opinions are related solely to claimed uranium emissions from Apollo during its period of operations. (Ring Dep. at 58:19-59:15; 60:11-19; 64:7-20; 124:14-18; 132:12-19.) Dr. Ketterer agreed in his deposition that his study suggests that uranium only – and no other radionuclide – was released from Apollo within 2.5 km from the site. (Ketterer Dep. at 129:20-132:11.) His study does not make a showing that any radionuclide was released from Parks. In fact, his study demonstrates the opposite. (Id. at 177:3-22.)

Plaintiffs point to one soil sample from Dr. Ketterer “indicat[ing] plutonium activity” right next to the Parks facility (Pls.’ Br. Opp’n at 29), but Defendants argue that it is undisputed that Plaintiffs have no evidence that anyone was exposed to this plutonium. Moreover, Dr. Ketterer confirmed under oath that his study, and this one sample, do not support the claimed release of any radionuclide, including plutonium, from Parks. (Ketterer Dep. at 85:6-89:20.)

Finally, Defendants argue that, to the extent that Dr. Melius’s causation opinions are based on exposure to radionuclides other than uranium, they also lack foundation. Dr. Melius’s opinions about various Plaintiffs include the statement that “exposures to uranium and other radioactive materials released from the Apollo nuclear facility made a significant contribution to the development of [the Plaintiff’s cancer].” However, Defendants maintain that, nowhere in his report, nor in any of Plaintiffs’ other five expert reports (as confirmed by their unequivocal deposition testimony), is there any support for the theory that any radionuclide, besides uranium, was released from the Apollo facility. (Ring Dep. at 58:19-59:15; 60:11-19; 64:7-20; 124:14-18; 132:12-19.) Dr. Melius assumes exposures to Plaintiffs that are not connected to any releases in excess of the federal permissible limits. (Melius Dep. Vol. I at 308:3-309:17; 309:21-311:6).

Defendants contend that it is undisputed that there is no evidence supporting the allegation that any Plaintiff was exposed to radionuclides other than uranium. Therefore, they request that the Court apply its CMO to make clear that uranium is the only relevant radionuclide with regard to “exposure, dose, or causation.”

The Court concludes that Defendants have demonstrated that Plaintiffs have not presented prima facie evidence of exposure to radionuclides other than uranium. Therefore, pursuant to paragraph 1(a) of the CMO, Plaintiffs will not be allowed to pursue, offer or rely upon evidence referring or relating to any claim based upon exposure to a radionuclide other

than uranium.

CMO ¶ 1(b): Identifying Exposure Pathways

Plaintiffs contend that Dr. Ketterer identifies an atmospheric exposure pathway and Mr. Franke concludes that highly enriched uranium was released in an airborne pathway in 1963.

Defendants assert that Mr. Franke assumes a hypothetical airborne exposure pathway for unnamed “members of the public who were present in the vicinity of the [Apollo] plant” during an alleged 1963 uranium release (Franke Rpt. ¶¶ 3-7), but he admits this calculation is irrelevant for CMO compliance purposes because he makes no attempt to connect it to a single Plaintiff. (Franke Dep. at 45:13-19.) Dr. Ketterer testified generally that his study supports an “airborne” exposure pathway, but he too did not connect any airborne releases to an actual Plaintiff. (Ketterer Dep. at 75:3-23.) He was not asked to do that work. (*Id.* at 37:11-38:7.) Defendants contend that, other than Dr. Ketterer’s generic claim that some Plaintiff might have been exposed to “airborne uranium,” none of Plaintiffs’ experts support any of the other “exposure pathways” that they have alleged for over two years including exposure to radionuclides in the river, groundwater, or from fixed sources within Defendants’ facilities.

Defendants note that Plaintiffs admit they are “not pursuing claims that their cancers are primarily caused by pathways other than inhalation,” but they claim that “waterborne contamination is still relevant” (Pls.’ Br. Opp’n at 31), arguing that “several Plaintiffs swam in the [Kiskiminetas River] and would have received direct exposure to radiation from the water,” citing the report of Dr. Melius. When asked about a potential water exposure pathway at his deposition, however, Dr. Melius admitted that: (a) no Plaintiff has reported that he or she drank water from the river; and (b) he has no evidence that water from the river was contaminated with any radionuclides. (Melius Dep. Vol. I at 123:23-124:4.) (Q: “You know of no evidence that the

Plaintiffs consumed drinking water contaminated with radionuclides or radiation from the Defendants' facilities, is that correct?" A: "Correct."). Moreover, he can point to no evidence that water from the river was contaminated with any radionuclides. (*Id.* at 127:14-19 (Q: "So to confirm, you have no information regarding levels of contamination or radiation in the river; is that correct?" A: "Correct." (objection omitted))). Nor do any of Plaintiffs' other experts discuss the Kiskiminetas River as a potential source of exposure. Therefore, they contend that Dr. Melius's assumptions regarding exposure pathways other than airborne releases lack scientific basis.

Defendants also note that Mr. Franke was not asked to – and did not – calculate even a hypothetical dose from a water source. (Franke Dep. at 28:10-19.) Therefore, Defendants assert that Plaintiffs' experts present no evidence for the claim that any Plaintiff was exposed to radiation through a waterborne pathway, or any other pathway except inhalation and request that the Court apply its CMO to make clear that inhalation is the only identified exposure pathway supported by *prima facie* evidence.

The Court concludes that Defendants have demonstrated that Plaintiffs have not presented *prima facie* evidence of exposure through pathways other than an airborne exposure to uranium. Therefore, pursuant to paragraph 1(b) of the CMO, Plaintiffs will not be allowed to pursue, offer or rely upon evidence referring or relating to any claim based upon exposure through a pathway other than airborne exposure to uranium.

CMO ¶ 1(c): Identifying Facilities and Dates of Exposure

Plaintiffs assert that Dr. Ring indicated that both Apollo and Parks facilities had a disregard for health and safety regulations and released radionuclides in excess of federal limits during their years of operation, Dr. Ketterer found soil contaminated with highly enriched

uranium in the vicinity of the Apollo and Parks facilities and Dr. Melius indicated that Plaintiffs were likely exposed to radionuclides from the Apollo and Parks facilities thereby enhancing the risk that they would contract the cancers they did.

Defendants argue that Plaintiffs' expert submissions do not provide any specific dates of exposure for any Plaintiff. They contend that Mr. Franke's "dose reconstruction" for a hypothetical individual from an alleged airborne release of uranium from the Apollo facility for fifteen minutes in 1963 does not meet the CMO's requirement because Franke admits he has no basis to state whether – let alone when – any Plaintiff was exposed due to this alleged event. He concedes his dose range in 1963 is merely a hypothetical "scenario calculation." (Franke Dep. at 45:13-19.) He neither asked for nor received any Plaintiff-specific information, despite knowing that it is required to perform a dose calculation. (*Id.* at 39:3-12.) His report does not address when an actual Plaintiff was exposed. (*Id.* at 140:2-6.)

Similarly, they contend that Dr. Ketterer's conclusion that uranium was released from Apollo, and can be found within 2.5 km of the facility using very sensitive equipment, says nothing about whether a particular Plaintiff was exposed to these background levels of uranium. Indeed, Dr. Ketterer agreed that his study is incapable of proving when the uranium detected might have been released from Apollo. (Ketterer Dep. at 76:3-11.)

Defendants argue that Plaintiffs' expert submissions and corresponding deposition testimony reflect the absence of evidence that any Plaintiff was exposed to radionuclides from the Parks facility. Dr. Ketterer, who tested the soil in several locations surrounding the Parks facility, testified that his study does not establish the presence of emissions from the Parks facility into the community. (Ketterer Dep. at 177:3-22.) Dr. Ring testified that he has no opinion whether radionuclides were released from Parks. (Ring Dep. at 62:20-63:13; 132:10-11;

196:9-10) (“I didn’t look at Parks.”). Finally, Mr. Franke – Plaintiffs’ sole dose expert – testified unequivocally that he did not calculate a dose to any Plaintiff from Parks because he has no evidence of a release from Parks, let alone any exposure. (Franke Dep. at 24:10- 16; 137:24-138:3.)

Defendants contend that Plaintiffs point to one soil sample from Dr. Ketterer “indicat[ing] plutonium activity” right next to the Parks facility (Pls.’ Opp’n at 29), but that they have no evidence that anyone was exposed to this plutonium. Moreover, Dr. Ketterer confirmed under oath that his study, and this one sample, do not support the claimed release of any radionuclide, including plutonium, from Parks. (Ketterer Dep. at 85:6-89:20.)

Plaintiffs also rely on excerpts from Dr. Ring’s report in which he argues that the environmental monitoring program at Parks was inadequate. (Pls.’ Opp’n at 29) (citing Ring Rpt. at 6, 22). Defendants respond that Dr. Ring acknowledged in his deposition that he “didn’t look at Parks,” and he has offered no opinion that any Plaintiff was exposed to radiation from that facility. (Ring Dep. at 62:20-63:13; 132:10-11; 196:9-10.)

Defendants assert that Dr. Melius’s causation opinion is based on the assumption that certain Plaintiffs were exposed to radionuclides from the Parks facility, but this assumption lacks foundation. Plaintiffs’ experts admit there is no evidence that any Plaintiff was exposed to radionuclides from Parks. Dr. Ketterer testified that his soil sampling study does not support the claimed release of any radionuclide from Parks and, in fact, proves the opposite. (Ketterer Dep. at 85:6-89:20; 177:3-22.) Mr. Franke – Plaintiffs’ sole dose expert – testified unequivocally that he did not calculate a dose to any Plaintiff from Parks because he has no evidence of a release from Parks, let alone any exposure. (Franke Dep. at 24:10-16; 137:24-138:3.) Dr. Ring, Plaintiffs’ “radiation protection practices” expert, testified that he has no opinion whether

radionuclides were released from Parks. (Ring Dep. at 62:20-63:13; 132:10-11; 196:9-10 (“I didn’t look at Parks.”)).

Defendants observe that Plaintiffs have abandoned the notion that some Plaintiffs may have been exposed to radionuclides related to the Shallow Land Disposal Area (SLDA) at the Parks facility. (Pls.’ Opp’n at 30.) Even though Plaintiffs acknowledge that they “are not seeking damages for injuries caused by exposure to the SLDA,” they argue that Defendants’ requested relief as to this site should be denied. (Pls.’ Opp’n at 33) (“Defendants’ May 30 and June 14 Motions should be denied in their entireties.”).

Defendants request that the Court apply the CMO to make clear that only the Apollo facility is at issue and that Plaintiffs have failed to present prima facie evidence of dates of exposure. The Court concludes that Defendants have demonstrated that Plaintiffs have not presented prima facie evidence of exposure from facilities other than Apollo. However, Plaintiffs have presented prima facie evidence that this exposure occurred during the years of operation of the Apollo facility and Defendants have not explained how Plaintiffs could be more specific when there was no “event” such as the accident at Three Mile Island to pinpoint a date of exposure. In addition, another reason Plaintiffs may not be able to provide more specific information regarding exposure dates is because Defendants failed to conduct adequate monitoring at the facility. See Hall, 69 F. Supp. 2d at 720-21 (“it would be most unfortunate if Plaintiffs were made to bear the burden of Defendants’ past non-compliant action with regard to monitoring.”). The Court concludes that Plaintiffs have met their prima facie burden by identifying the dates of operation of the Apollo facility.

Therefore, pursuant to paragraph 1(c) of the CMO, Plaintiffs will not be allowed to pursue, offer or rely upon evidence referring or relating to any claim based upon exposure from a

facility other than the Apollo facility during its years of operation.

CMO ¶ 1(d): Identifying a Numerical Dose

Plaintiffs contend that Mr. Franke's report, showing that Defendants regularly and repeatedly violated the standard of care regarding the release of radionuclides at the Apollo and Parks facilities, supports their requirement to identify a numerical dose. They also contend that, although Mr. Franke did not perform a dose reconstruction for each Plaintiff in this case, Dr. Melius has explained that, because of the inherent unreliability of the environmental monitoring data at the Apollo facility, there was minimal value in doing a numerical dose reconstruction because any such analysis would significantly understate any individual's exposure. (Melius Dep. II at 376:18-378:7.) Moreover, they note that Dr. Doetsch reported that there is no level of ionizing radiation exposure that has been found to be non-carcinogenic in humans. (Doetsch Rpt. at 9.)

Defendants respond that Mr. Franke did not perform a dose reconstruction for any Plaintiff because he lacks all of the information he acknowledges is needed to calculate a Plaintiff-specific dose. (Franke Dep. at 39:3-12.) He admits his report does not address the CMO's dose requirement (*id.* at 29:22-30:2) and instead reserves the right to provide a more "detailed assessment" of Plaintiffs once he receives information that has essentially been available to him for years. (Franke Rpt. ¶ 9.)

Defendants maintain that Plaintiffs' position about the minimal value of performing dose reconstruction is in direct contradiction to their own expert, Mr. Franke, who twice filed reports in these actions stating he is "prepared to provide a detailed assessment of the radiation exposures for specific individuals." *See* Franke Rpt. ¶ 9; *id.* at 68 (Chapter 9 titled "Assessment of doses to individual residents"). Defendants state that it is possible to quantify estimated doses

(if any) for each Plaintiff, and that it cannot be disputed that individual dose is critical to determining causation. They note that Plaintiffs' Opposition, moreover, does not claim that they need more discovery or further opportunity to develop and present reliable dose estimates for each Plaintiff. The Plaintiff-specific information Mr. Franke claims to need has been available to him for years. Defendants contend that Plaintiffs have made a calculated decision not to provide estimated radiation doses for each Plaintiff, and they have failed to comply with paragraph 1(d) of the CMO. They request that the Court apply paragraph 1(d) of the CMO to preclude Plaintiffs from pursuing, offering or relying upon evidence referring or relating to any claim based upon any dose to an individual Plaintiff.

Defendants are correct that Plaintiffs have not presented prima facie evidence of the numerical dose, if any, for each Plaintiff's claimed exposure to the specific radionuclides originating from the facility, even in form of dose reconstruction. However, to the extent that Defendants are arguing (by implication, if not explicitly) that this omission should result in Plaintiffs being unable to pursue their claims in any respect, they have exceeded the scope of the CMO and case management responsibilities of the undersigned and are arguing about the merits of the cases. In addition, Defendants have not responded to Plaintiffs' argument that Judge Ambrose explicitly rejected the argument in the Hall case that the experts' testimony submitted by the plaintiffs lacked sufficient foundation because it was not based on the specific dose a plaintiff might have received from the radiation emissions. Hall, 69 F. Supp. 2d at 721. Finally, Plaintiffs have presented evidence that no level of ionizing radiation exposure has been found to be non-carcinogenic in humans, and they can pursue their claims even without a specific dose calculation as to each individual Plaintiff.

The Court concludes that, although Plaintiffs have not presented prima facie evidence of

each Plaintiff's specific dose of exposure, such omission shall not preclude them from pursuing their cases relating to an airborne exposure to highly enriched uranium from the Apollo facility during its years of operation. Therefore, with respect to paragraph 1(d) of the CMO, the Court denies Defendants' motions.

CMO ¶ 1(e): Providing Epidemiological Evidence

Plaintiffs state that the reports of Dr. Doetsch and Dr. Hu support their prima facie cases of general and specific causation by explaining that ionizing radiation, such as highly enriched uranium, is capable of causing the injuries (specific kinds of cancer) alleged by the individual Plaintiffs. As noted above, Drs. Doetsch and Hu identified numerous cancers that can be caused by ionizing radiation and Dr. Melius has indicated that the Plaintiffs have these cancers.

Defendants respond that Dr. Doetsch admits that his report does not address any of the CMO's requirements. (Doetsch Dep. at 25:22-30:1 (responding "no" to questions about whether his report addresses each subsection of the CMO). Dr. Doetsch does not cite to – nor did he review – any relevant epidemiological studies. (*Id.* at 46:8-13; 48:25-49:14.) Plaintiffs' other general causation expert, Dr. Hu, cites to no epidemiological evidence that uranium can cause the Plaintiffs' types of diseases. He admits that he does not even know Plaintiffs' types of cancer or disease. (Hu Dep. at 153:5-13.)

Defendants assert that Plaintiffs are attempting to shift the burden of proof. Dr. Hu claims that the "[t]he lack of epidemiologic studies demonstrating significantly elevated risks of cancer for each of the individual cancers listed above . . . CANNOT be construed as an indication that that (sic) the radionuclides cited above are incapable of causing the full range of cancers listed." (Hu Rpt. at 9.) They maintain that this assertion does not comply with the CMO. They contend that the "individual cancers" Dr. Hu refers to are 22 cancers referenced in

EEOICPA, a regulatory scheme for nuclear workers similar to workers' compensation. Dr. Hu indicated that he did not know if this list was compiled based on epidemiological studies of individuals exposed to uranium. (Hu Dep. at 182:22-183:18.)

Plaintiffs argue that Dr. Doetsch's report provides the fundamental building blocks for the opinions of the other experts and is clearly relevant to the issues at hand. Nevertheless, Plaintiffs have not produced epidemiological evidence in support of their claims. They will be required to proceed with the testimony of Dr. Hu and Dr. Doetsch that highly enriched uranium could be expected to constitute a substantial contributing factor towards the causation of Plaintiffs' cancers.

CMO ¶ 1(f): Providing Scientific and Medical Evidence

Plaintiffs contend that Dr. Ring's report provides scientific and medical evidence in support of their claims and that Defendants attempt to take advantage of their own failure to monitor to assert that Dr. Ring cannot quantify the releases. They further assert that Dr. Doetsch and Dr. Hu provide evidence of the scientific and medical evidence in support of their claims.

Defendants respond that Plaintiffs' expert submissions taken together provide no Plaintiff-specific scientific or medical evidence amounting to a prima facie showing of any individual Plaintiff's alleged exposure, dose and causation. Further, they contend that Plaintiffs merely offer generic theories as to how Plaintiffs, as a group, were supposedly harmed.

The Court concludes that Plaintiffs have produced some evidence in support of their claims. However, for the reasons expressed above, they have not produced scientific and medical evidence providing the basis for and supporting each of the prima facie elements of each Plaintiff's claim. They will be required to proceed with the evidence they have produced as to the prima facie elements of each Plaintiff's claim.

AND NOW, this 12th day of September, 2012,

IT IS HEREBY ORDERED that Defendants' Motions Regarding Plaintiffs' Failure to Comply with Case Management Order are granted in part and denied in part, as follows:

1. Plaintiffs may not pursue, offer, or rely upon evidence referring or relating to any claim based on the theory of exposure of any radionuclide from the Parks Township Facility or the Shallow Land Disposal Area (or Facility);
2. Plaintiffs may not pursue, offer, or rely upon evidence referring or relating to any claim based on the theory of exposure to any radionuclide other than enriched uranium; and
3. Plaintiffs may not pursue, offer, or rely upon evidence referring or relating to any claim based on the theory of exposure via any pathway other than inhalation of enriched uranium released into the air from the Apollo Facility during its period of operation.

In all other respects, Defendants' motions are denied.

s/Robert C. Mitchell
ROBERT C. MITCHELL
United States Magistrate Judge